

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Mark Shu et al.	Examiner:	Alvin J. Stewart
Serial No.:	10/792,186	Group Art Unit:	3738
Filed:	March 3, 2004	Docket:	M190.148.101 / P0011480.00
Due Date:	November 4, 2009		
Title:	SUTURE LOCKING ASSEMBLY AND METHOD OF USE		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant filed a Notice of Appeal and requests review of the Final Rejection in the pending application. Please consider the following remarks during the Pre-Appeal Brief Conference.

Independent claim 1 is currently pending, as are claims 2-31 and 54-58. In the Final Office Action mailed August 4, 2009 ("FOA"), claim 1-31 and 54-58 were rejected as being anticipated by Alonso, USPN 4,935,030 ("Alonso"). For the reasons below, Applicant believes that claim 1 is not anticipated by Alonso. In addition, many claims depending from claim 1 recite features that clearly define over Alonso, but are not addressed in any way by the FOA (or the Advisory Action mailed October 19, 2009). While the FOA provides an explanation of the rejection of claim 1, the remaining claims, and in particular claims 20, 21, and 54-58, are essentially unexamined and Applicant is unfairly prevented from presenting a meaningful response. Withdrawal of the rejections and/or removal of the finality of the FOA is requested.

Independent Claim 1

Independent claim 1 relates to a suture locking assembly for use with a heart valve repair device, with the suture locking assembly comprising a rim and a suture band. The rim defines a first flange spaced from a second flange; the suture band is maintained between the flanges. Relative to a circumferential interface between the rim and the suture band, a radial spacing between the rim and the suture band decreases from a first radial spacing to a second radial spacing. One example of this relationship is shown in FIGS. 32, 34a and 34b (reproduced below).

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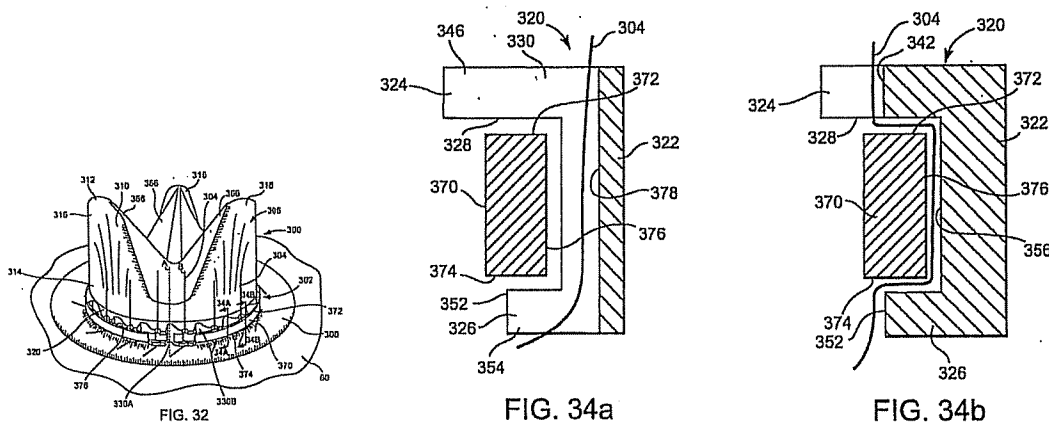
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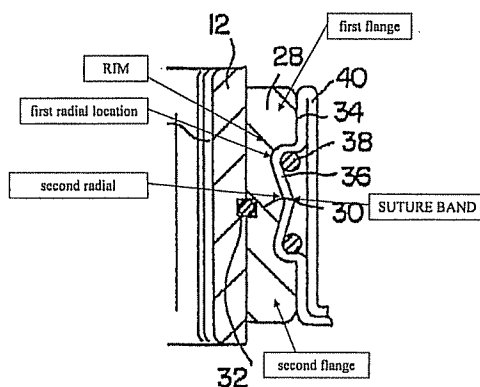
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Alonso discloses a mechanical heart valve prosthesis including mechanical leaflets 14 pivotably attached to an annular base 12. A conventional sewing ring 40 is mounted to the annular base 12 by a metal ring 28 via threads 38. The FOA interprets the metal ring 28 as being the “rim” of claim 1 and the sewing ring 40 as being the claimed “suture band”. The FOA points to thread-receiving grooves in the rim/metal ring 28 as teaching the radial spacing features as claimed, incorporating a portion of the view of FIG. 3 of Alonso to illustrate the Examiner’s interpretation of Alonso relative to claim 1. For ease of explanation, a similar portion of FIG. 4 is reproduced below, along with the FOA’s designations as best understood.



While it is agreed that the rim/metal ring 28 of Alonso forms opposing grooves (i.e., the “first radial location” above) opposite a radially projecting center point (i.e., the “second radial location” above), this surface feature does not teach the limitations of claim 1. Claim 1 recites

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that the rim defines spaced apart flanges, with the suture band being maintained between the first and second flanges. Given this explanation, the only portion of the sewing ring 40 of Alonso that can serve as the “suture band” of claim 1 is the length of material between the threads 38 and otherwise in contact with the face of the rim/metal ring 28. All other portions of the sewing ring 40 are not between the rim flanges. With this understanding in mind, and as clearly illustrated above, the suture band/sewing ring 40 of Alonso uniformly contacts the rim/metal ring 28 between the flanges. As such, even though the rim/metal ring 28 may define the central radial projection, the assembly as a whole does not provide any radial spacing between the rim/metal ring 28 and the suture ring/sewing ring 40, in direct contrast to claim 1.

The Advisory Action appears to concede that the above interpretation of Alonso is correct, but argues instead that the claimed phrase “radial spacing” does not require an “open space” between the rim and the suture band because claim 1 “is not positively claiming that open space”. Applicant disagrees. The term “spacing” is more than just a name; the Advisory Action’s assertion that a claimed “spacing” does not require a “space” fails to properly give a reasonable interpretation to the claim language. Simply stated, a “spacing” is a “space” and the fact that Alonso does not have any space between the rim/metal ring 28 and the suture band/sewing ring 40 dictates that Alonso cannot anticipate claim 1.

Even further, assuming *arguendo* that “spacing” of claim 1 does not require an “open space,” claim 1 further requires that the claimed “radial spacing” decreases from a first radial spacing to a second radial spacing. Given this, even if Alonso’s “absence” of an open space could reasonably be interpreted as teaching a “radial spacing,” this “absence of an open space” between the rim/metal ring 28 and the suture band/sewing ring 40 of Alonso is uniform along an entire circumference of the Alonso prosthesis. Thus, Alonso cannot teach “a radial spacing between the rim and the suture band decreases from a first radial spacing to a second radial spacing” as claimed. Alonso only provides “no” radial spacing and thus cannot teach a decreasing spacing between two circumferentially adjacent locations.

In addition, claim 1 recites that the suture locking assembly is configured to securely maintain a suture segment that is circumferentially pulled relative to at least one of the flanges

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from a first position to a second position. The FOA and Advisory Action fail to address this claimed feature in any way. Nothing in Alonso discloses that the metal ring 28/sewing ring 40 as being configured to securely maintain a circumferentially-pulled suture segment.

For at least the above reasons, claim 1 is not anticipated by Alonso. Withdrawal of the rejection is respectfully requested.

Claims Depending From Independent Claim 1

In a Response After Final filed October 5, 2009, Applicant specifically highlighted claims 20, 21, and 54-58 as reciting features not found in Alonso, and not addressed in the FOA. The FOA and the Advisory Action fail to acknowledge or consider any of these deficiencies. In short, the FOA's blanket rejection of the claims highlighted below as somehow being anticipated by Alonso without an even cursory reference to corresponding features in Alonso dictates that the rejections be withdrawn; it is impossible for Applicant to address the rejections without at least some understanding of how the Examiner is interpreting Alonso as teaching each and every claimed feature. In the interest of brevity, distinguishing features of each of these claims are summarized below.

Claim 20 recites a plastic cover, and the suture band maintained between the rim and the cover. The FOA fails to identify any corresponding teachings in Alonso, and none exist.

Claim 21 recites the suture band formed of a metallic material. The FOA fails to identify any corresponding teachings in Alonso, and none exist. The suture band/sewing ring 40 of Alonso is fabric.

Claim 54 recites that perimeter shape of the first flange differs from that of the second flange. The FOA fails to identify any corresponding teachings in Alonso, and none exist. The identified "flanges" of the rim/metal ring 28 of Alonso have an identical perimeter shape.

Claim 55 recites the first flange forms a first pattern of radial indentations, and the second flange forms a different, second pattern of radial indentations. The FOA fails to identify any corresponding teachings in Alonso, and none exist. The flanges of the rim/metal ring 28 of Alonso do not have radial indentations, let alone differing patterns.

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Claim 56 recites the first flange forms a plurality of recesses and grooves, with a depth of the recesses being greater than a depth of the grooves. The FOA fails to identify any corresponding teachings in Alonso, and none exist. The flanges of the rim/metal ring 28 of Alonso do not have recesses or grooves, let alone recesses/grooves of differing depth.

Claim 57 recites the rim forms a plurality of recesses, with each of the recesses being non-symmetrical. The FOA fails to identify any corresponding teachings in Alonso, and none exist. Neither of the flanges of the rim/metal ring 28 of Alonso has recesses, let alone non-symmetrical recesses.

Claim 58 recites each recess is defined by leading and trailing surfaces extending from a lateral edge, and an angle of extension of the leading surface differs from that of the trailing surface. The FOA fails to identify any corresponding teachings in Alonso, and none exist. Neither of the flanges of the rims/metal ring 28 of Alonso has recesses, let alone recesses defined by surfaces with differing angles of extension.

Any inquiry regarding this Communication should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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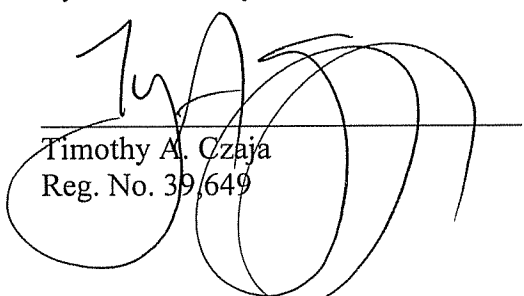
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Respectfully submitted,

Mark Shu et al.,

By their attorneys,

Date: November 4, 2009
TAC:jms



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